



Regulatory Audits: Strategies for Avoiding Common Audit Triggers



The increasing globalization of businesses under is causing regulatory agencies to increase their focus on data integrity and critical thinking. Here are some strategies for steering clear of common audit triggers and maintaining data integrity in a regulated environment.

What are the most common regulatory audit triggers?

- **Limited traceability and transparency**
Regulators expect companies to move from paper-based/hybrid systems to electronic systems for full data traceability.
- **Poor data governance**
Regulators want companies to take a holistic, risk-based approach to data throughout its life cycle. That means proper risk analysis across all data sources should be in place to identify critical data points.
- **Failure to meet predicate rules and 21 CFR Part 11 requirements**
Data must be Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available (ALCOA+).



What should a robust electronic data review process include?

Many companies fail regulatory audits because they limit their data review to audit trails and reports. Your electronic data review process should consist of:

- Source e-data with the associated metadata and audit trails
- Server activity logs
- Operating system-specific activity logs
- Application-specific activity logs
- Instrument error logs
- IT tickets (to check backend database changes for modified or deleted data)
- Result sets

How can we ensure data security?

Regulators want companies to have prevention and detection mechanisms in place to ensure that data is secure and controlled. Ask yourself these questions:

- Is our source e-data secured in a controlled environment?
- Do we review our source e-data?
- Does our source e-data include meaningful metadata with audit trails?
- Do we have proper segregation of duties?
- Are our systems validated per their intended use by both sponsors and contract manufacturers?

Learn more about the paradigm shift in regulatory audits and what it means for analytical laboratories. View the on-demand webinar: *Addressing the Paradigm Shift in Regulatory Inspection*
www.agilent.com/chem/regulatory-inspections-webinar

Learn more about keeping your data consistent, accurate, and protected.
www.agilent.com/chem/openlab-cds-data-integrity

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Published in the USA, October 1, 2018
5994-0295EN